SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

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DENISE BROUARD and GERALD BROUARD,

Plaintiff,

Index No.: 28560/05

-Against-

Affirmation

JAMES CONVERY, P.V. HOLDING CORP. and
AVIS RENT A CAR SYSTEM, INC.,

Defendants.

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APOSTOLOS JOHN TSIOURIS, M.D., being duly sworn, deposes, says and affirms the truth of the following matters under penalty of perjury:

1. I am a staff neuroradiologist at The NewYork-Presbyterian Hospital – Weill Cornell Medical Center in New York City. My rank is Associate Professor of Clinical Radiology. I have 15 years of experience in a very active clinical neuroradiology practice, in which I primarily interpret CT and MRI scans of the brain and spine. I am currently actively involved in investigating diffusion tensor imaging (DTI) for the evaluation of mild traumatic brain injury as part of an ongoing collaborative research studies with the Hospital of Special Surgery (NY, NY) and the department of Neurosurgery at Weill Cornell Medical Center. I routinely analyze and review DTI data sets for the purposes of neurosurgical brain tumor pre-operative planning. I lead and moderate weekly multidisciplinary neurovascular and neurosurgery conferences.

2. I have testified as an expert in other proceedings relative to my expert opinions and knowledge and I will testify in Court at any hearings and/or trials as required. All of my opinions herein are stated with a reasonable degree of medical and scientific certainty.

3. My duly sworn affidavit dated 8/22/16, an exhibit to the original motion at issue herein is annexed hereto, incorporated by reference as though more fully set forth at length herein and for the Court's convenience and to further set forth my qualifications. All of my prior sworn statements still hold 100% true. There are a few points on Plaintiff's motion to Reargue/Renew that needs to be addressed.

4. First, as a reminder, I pointed out in my original affirmation how Dr. Lipton published a peer review article, which concluded that the DTI technique he was using since 2003 or 2004 is obsolete and inaccurate. This is important because in Dr. Lipton and Plaintiff's efforts to utilize DTI in lawsuits they claim that DTI has been generally accepted for over a decade and rely on peer reviewed papers from the mid 2000's and forward. Initially, it's been pointed out previously how those articles they rely upon actually concluded that DTI is not appropriate for use to assess TBI in single subject patients. That said, Dr. Lipton's recent article does establish one very important thing. Namely, that the state of DTI science and research since 2003 has let us know that his old DTI methods are not generally accepted. Consequentially, any reliance on prior Court Decisions regarding DTI are rendered based upon outdated information.

5. I have read Your Honor's February of 2018 decision and agree that it reflects the state of DTI science at present time (and at the time the motion was made and decided), i.e. that DTI is not generally accepted for assessment, diagnosis or prognostication of a traumatic brain injury in a single subject patient. A common occurrence in medical research is that methods and results once thought to be appropriate and generally accepted are later discovered to be prone to various errors/issues that prove them invalid with additional investigation. That is what has occurred here.

6. This leads us to the second point. IF DTI really was generally accepted then why would the American College of Radiology (ACR) sponsor and endorse the White Paper written by Wintermark et al. and titled "Imaging Evidence and

Recommendations for Traumatic Brain Injury: Advanced Neuro and Neurovascular Imaging Techniques" was published in the American Journal of Neuroradiology on November 25, 2014? The Answer of course is that there would be no such need for the white paper and therefore the fact that one had to be written and endorsed by the medical/scientific community is informative on the fact that DTI is not a generally accepted modality for assessment of TBI in a single subject patient.

7. As one of the coauthors on the paper I can absolutely refute the baseless claims that the White Paper is not scientific. Nothing could be further from the truth. As previously attested, this medical consensus paper was written by members of the ACR's Head Injury Institute (HII) to help guide appropriate imaging for patients suffering from traumatic brain injury. Co-first author of this publication is Dr. Pina Sanelli, who is currently the president of the American Society of Neuroradiology, holds a Masters in Public Health from Harvard Medical College and the EVIDENCE BASED MEDICINE CO-CHAIR of the American Society of Neuroradiology (ASNR).

The available peer reviewed DTI literature in the setting of TBI was systematically reviewed by the paper's co-authors in order to come to a conclusion on the acceptable/non-acceptable use of DTI in the setting of TBI. This is peer review. Moreover, as a second layer of peer review the White Paper is reviewed by all of the listed doctors and medical/scientific communities that endorsed the findings of the paper. To say the paper is not scientific and/or not peer reviewed is outright false. IF anything it maintains one of the highest level of peer reviews as it reviewed all the available data up to that point in time to reach a consensus by the medical/scientific community that DTI does not (at the time of this writing) have a general acceptable to be used on individual patients for the treatment, diagnosis, prognosis or assessment of TBI. I would also like to point out that the footnotes the White paper cite to over 160

peer reviewed articles. Additionally, as I pointed out in my original affidavit, that list would have been larger, but due to word count limitations imposed by the journal, could not all be included.

8. Further to the point of the White Paper absolutely being a scientific paper relied upon for its methods and conclusion that DTI is not generally accepted for use in single subject TBI settings, Dr. Lipton, as a member of the ACR's Head Injury Institute (HII) at the time the white paper was written, reviewed the draft prior to publication and was given the opportunity to edit and make recommendations/suggestions before publication. Many of his comments in his original Affirmation were included in an email to the entire ACR HII group of physicians reviewing and editing the white paper. His suggestions were thoughtfully considered by the ACR HII committee, but mostly rejected. He was the *only* physician on the ACR HII to not endorse this publication.

9. Dr. Lipton being the sole member of the ACR HII group not to endorse the Paper is very significant to the issues before this Court. It shows how this is not a situation where there is a split in the medical/scientific community about the use of DTI in single subject TBI patient settings, but rather that there is a generally accepted consensus and position that DTI is not appropriate to be used in such a manner and that Dr. Lipton is a sole detractor of this fact.

10. After the White Paper was published, and after this Court's February of 2018 Decision to preclude DTI (relying on the White Paper, affidavits, and other articles/evidence submitted to the Court) based Frye standards, the Radiological Society of North America updated its statement on Traumatic Brain Injury (TBI) imagining on April 15, 2018. A copy of the Statement is annexed to this affidavit and it is a publically available document on their website at https://www.rsna.org/uploadedFiles/RSNA/Content/Role_based_pages/Media/RSNA-

TBI-Position-Statement.pdf. This statement concludes in the same manner as the White Paper and this Court's February of 2018 decision:

> Advanced neuroimaging techniques, including MRI diffusion tensor imaging, functional MRI, MR spectroscopy, perfusion imaging, PET/SPECT and magnetoencephalography, are of particular interest in identifying further injury in TBI patients when conventional non-contrast head CT and MRI are normal, as well as for prognostication in patients with persistent symptoms. At present, there is insufficient evidence supporting the routine clinical use of these advanced neuroimaging techniques for diagnosis and/or prognostication at the individual patient level. This is the focus of ongoing research.
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> *RSNA is a strong advocate for quality, safety and strict adherence to appropriateness criteria in medical imaging and radiation oncology. Through its peer-reviewed journals and education programs, RSNA continually informs radiologists, medical physicists, radiation oncologists and other radiology professionals of the latest technologies and research developments designed to optimize dose and improve patient safety.*

11. The RSNA is an international society of radiologists, medical physicists and other medical professionals with more than 54,000 members from 136 countries. Ever year in late November/early December, the RSNA hosts the world's premier radiology forum in Chicago, IL, drawing approximately 55,000 attendees annually. The RSNA also publishes the journal *Radiology*, the highest-impact scientific journal in the field, and *Radiographics,* the only journal dedicated to continuing education in Radiology. Through its educational resources, the RSNA provides hundreds of thousands of continuing medical education credits to radiologists maintenance of certification. The society also develops informatics-based software to support a universal electronic medical record, sponsors research to advance quantitative imaging biomarkers (such as DTI), and provides millions of dollars to fund investigators in radiology

12. The RSNA periodically issues position statements on several radiology-related topics. These statements are reviewed annually and updated as new information and technology becomes available and are based on the best possible available peer-reviewed scientific evidence and expert opinions.

13. The RSNA statement is further confirmation that the state of scientific evidence regarding DTI at present time, the White Paper, and Your Honor's February of 2018 decision all correctly stand for the principle that DTI is not currently a Generally accepted modality for use in single subject TBI settings. In short, the relevant scientific/medical community, via the RSNA, confirms that your Honor was correct to find that DTI should be precluded in lawsuits under Frye standards.

14. There is however even more new evidence that DTI is not generally accepted which was also not available at the time of the original motions in this case. "Effect of career Duration, Concussion History, and Playing position on White Matter Microstructure and Functional Neural Recruitment in Former College and Professional Athletes" was published in *Radiology*: Volume 286: Number 3 in March of 2018. This research study compared a group of collegiate football players with a history of zero or one prior concussion with a group of collegiate players who had three or more concussions. They found that the high concussion collegiate group had lower mean FA values than the low concussion collegiate group. HOWEVER, when the test was repeated with pro-football players, THE OPPOSITE RESULTS WERE FOUND. The high concussion pro-football group had higher mean FA values than the low concussion pro-football player group. Furthermore, the high concussion pro-football group had the highest FA values of all four groups. It is also important to note, that all 61 participants in this study were cognitively normal regardless of concussion history, years of play and FA values. Therefore, the lower mean FA values found in the high concussion collegiate group did not correlated to any cognitive deficits.

15. This is immensely important to the current state of DTI. Plaintiff is espousing the theory that they can assess TBI via comparing the single patient/plaintiff's FA to a group of non-injured people and if the Plaintiff's FA is lower than the average of the non-injured people it indicated a TBI. This research paper finds the opposite. professional football players who had numerous concussions had no difference in FA than college players with no concussions and higher FA than pro-football players with no concussions. Therefore, this peer reviewed article supports the position that DTI and FA analysis cannot currently be used as a valid assessment of TBI in a single subject patient, especially where even the group based studies are presenting unexpected results.

Specifically, the authors of the article state that they:

> "do not have the data to explain this result, **but speculate** that this lack of difference may reflect a selection bias in favor of former professional players with a relatively high amount of brain reserve."
>
> **[Emphasis Added]**

16. The fact that they can only speculate why the purported theory that high concussion rate and/or TBI did not produce lower FA levels in older more concussed players than younger player with no concussion (and also with higher FA than similarly aged older player with no concussions) further supports the generally accepted medical and scientific consensus that DTI cannot be used to assess single subjects with TBI. If research studies are still showing the exact opposite results to Plaintiff and Dr. Lipton's theories and the only way to reconcile those results with Dr. Lipton and Plaintiff's theory is through speculation, it is clear that DTI still needs more research and is not yet generally accepted in the non-research TBI setting. This article falls perfectly in line with the findings form the White Paper, Your Honor's February of 2008 decision and the statement from the RSNA.

17. Next, I must address the persistently made false claims that DTI is used at NewYork-Presbyterian Hospital. DTI HAS NEVER BEEN UTILIZED FOR ANY CLINICAL PURPOSE RELATED TO TRAUMATIC BRAIN INJURY AT THE NEWYORK-PRESBYTERIAN HOSPITAL. DTI is used exclusively in the research context at my hospital. Plaintiff's sole basis for this false claim is a 2010 flyer. As I pointed out in my original affidavit, the flyer clearly states it was being used to recruit patients for a GROUP based study; the purpose of this study was to investigate if DTI can be used to diagnose concussions. The NewYork-Presbyterian Hospital has never and currently does not use DTI in individual patients with TBI because the technique is not generally accepted and has not been scientifically validated.

18. Please take notice that any issue not addressed in this affidavit is not to be taken as a consent to the Plaintiff's position. Rather, my original affirmation debunks all of their theories. This instant affidavit is submitted to inform the Court of new information not in existence at the time the original motions were submitted and ot stress some of the very important points and inaccurate arguments made by Plaintiff and Dr. Lipton. I again refer the Court to my annexed original affirmation, read in conjunction with this affidavit, for a complete discussion as to why DTI is not generally accepted[1]

Dated: July 16, 2018

Apostolos John Tsiouris, M.D.

DANITA NORVILLE
Notary Public, State of New York
Registration #01NO6347798
Qualified In Queens County
Commission Expires Sept. 12, 2020

Danita Norville 07/16/2018

[1] Notably the RSNA and White Paper specifcally reference PET as well as not being appropriate for TBI assessment in individual patients.